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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
09/527,275	03/17/00	UNSICKER	K 2896.1002001

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HM22/0914

EXAMINER

CHERNYSHEV, O

ART UNIT	PAPER NUMBER
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1646

DATE MAILED:

09/14/01

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary

Application No.

09/527,275

Applicant(s)

UNSICKER ET AL.

Examiner

Olga N. Chernyshev

Art Unit

1646

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-56 is/are pending in the application.
- 4a) Of the above claim(s) 4, 6-15 and 17-56 is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 1, 2, 5 and 16 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claims ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are objected to by the Examiner.
- 11) ☐ The proposed drawing correction filed on ____ is: a) ☐ approved b) ☐ disapproved.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. ____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

- 15) ☒ Notice of References Cited (PTO-892)
- 16) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 17) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 5.
- 18) ☐ Interview Summary (PTO-413) Paper No(s). ____.
- 19) ☐ Notice of Informal Patent Application (PTO-152)
- 20) ☐ Other: _____.

DETAILED ACTION

Response to Amendment

1. The claims 1-16 have been amended and claims 17 -56 have been added as requested in the amendment of Paper #8, filed on July 12, 2001. Claims 1-56 are pending in the instant application.

2. Applicant's election with traverse of Group III, claims 1-2, 5 and 16 in Paper No. 8 is acknowledged. The traversal is on the ground(s) that the inventions presented are not distinct because claims of the instant application are directed to cytokines with common neurotrophic function. Applicants' arguments were fully considered but not found persuasive.

Applicants argue that presented inventions are not distinct since each claim recites different combination of cytokines, classified in the identical class and subclass. The Examiner disagrees with the Applicants' assumption that search of the literature for all possible combinations of presented cytokines (total thirteen) would not place a substantial burden on the Examiner. A family of cytokines is presently considered to be so immense that it includes superfamilies of growth factors itself, e.g. TGF- β superfamily. Each of known and newly discovered factors from this family represents unique molecular embodiment, most often a ligand for a specific receptor, or holds a specific biological activity. According to the current classification system, all the cytokines are classified together in one class/subclass. However, the claims presented in the instant application are clearly directed to independent and distinct inventions, since each group recites a distinctive combination of factors, which can be made and used without each other and are not required one for the other.

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Applicants' argument that in view of examination of claims 1 and 2, which contain all the elements of the thirteen restricted Groups has not been found persuasive because claim 1 and 2 are very broad claims, and the inventive groups encompass a unique combination comprising physically and functionally distinct chemical entities, requiring non-coextensive literature search.

The requirement is still deemed proper and is therefore made FINAL.

Claims 4, 6-15 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention, there being no allowable generic or linking claim.

Applicant timely traversed the restriction (election) requirement in Paper No. 8.

3. Newly submitted claims 17-56 directed to an invention that is independent or distinct from the invention originally claimed for the following reasons: new claims are directed to methods, which are not part of the elected invention directed to compositions. Inventions III and newly submitted inventions directed to different methods are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case composition of Group III could be used in entirely different manner, for example for studies of different activities possessed by presented cytokines, rather than in methods of newly submitted claims.

Accordingly, claims 17-56 are withdrawn from consideration as being directed to a non-elected invention. See 37 CFR 1.142(b) and MPEP § 821.03.

Claims 1-2, 5 and 16 are under examination in the present office action.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-2, 5 and 16 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

4. Claim 1 is indefinite for recitation of "biological active amount of". The metes and bounds of the phrase are not defined by the instant specification and are not clear (for example, active in what manner as it is assumed that any amount of cytokine would have biological activity). Also, "functionally active derivatives or parts thereof" phrase does not connect with the rest of the sentence, for it is not clear what is meant by functionally active derivatives and by parts of derivatives or the cytokines. Clarification is required.

5. Claim 2 is indefinite because it depends from claim 1, which recites two cytokines of a composition, so it is not clear to which group of two cytokines of claim 1 the cytokines of claim 2 belong to. Clarification is required.

6. Claims 5 and 16 are indefinite for being dependant from the indefinite claim.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

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A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

7. Claims 1-2 and 16 are rejected under 35 U.S.C. 102(b) as being anticipated by

Krieglstein et al. (Neurochem. Research, 21, No.7, pp.843-850, 1996).

Krieglstein et al. (1996) teach a composition having neurotrophic activity, comprising TGF- β and other cytokines (see the Abstract and Discussion on page 848, especially).

Also, the composition of Krieglstein et al. (1996) was used in culture medium (DMEM, see p. 844, Experimental Procedure), which meets the limitations of claim 16, where the composition of claim 1 further comprises a pharmaceutically acceptable diluent.

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

8. Claim 5 is rejected under 35 U.S.C. 102(a) as being anticipated by Louis (WO 97/19694, June, 1997).

Louis (WO 97/19694, June, 1997) teaches a composition having neurotrophic activity, comprising GDNF and TGF- β (see specification and claim 8).

Conclusion

9. No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Olga N. Chernyshev whose telephone number is (703) 305-1003. The examiner can normally be reached on Monday to Friday 9 AM to 5 PM ET.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Yvonne Eyler can be reached on (703) 308-6564. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 308-0294 for regular communications and (703) 308-0294 for After Final communications.

Certain papers related to this application may be submitted to Technology Center 1600 by facsimile transmission. Papers should be faxed to Technology Center 1600 via the PTO Fax center located in Crystal Mall 1 (CM1). The faxing of such papers must conform with the notices published in the Official Gazette, 1156 OG 61 (November 16, 1993) and 1157 OG 94 (December 28, 1993) (see 37 C.F.R. § 1.6(d)). NOTE: If Applicant *does* submit a paper by fax, the original signed copy should be retained by Applicant or Applicant's representative. NO DUPLICATE COPIES SHOULD BE SUBMITTED so as to avoid the processing of duplicate papers.

Official papers filed by fax should be directed to (703) 308-4556 or (703) 308-4242. If either of these numbers is out of service, please call the Group receptionist for an alternative number. Faxed draft or informal communications with the examiner should be directed to (703) 308-0294. Official papers should NOT be faxed to (703) 308-0294.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

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Olga N. Chernyshev, Ph.D. *OC*
September 9, 2001

CHRISTINE J. SAOUD
PRIMARY EXAMINER

Christine J. Saoud